

We Claim

1. A fluidic diagnostic device for measuring an analyte concentration or property of a biological fluid,

comprising

a first layer and second layer, at least one of which has a resilient region over at least a part of its area, separated by an intermediate layer, in which cutouts in the intermediate layer form, with the first and second layers,

a) a sample port for introducing a sample of the biological fluid into the device;

b) a first measurement area, in which a physical parameter of the sample is measured and related to the analyte concentration or property of the fluid;

c) a first channel, having a first end and a second end, to provide a fluidic path from the sample port at the first end through the first measurement area;

d) a first bladder, at the second end of the first channel, comprising at least a part of the resilient region in at least the first or second layer and having a volume that is at least about equal to the combined volume of the first measurement area and first channel; and

e) a first stop junction in the first channel between the first measurement area and first bladder that comprises a co-aligned through hole in the first or second layer, the through hole overlaid with a third layer.

2. The device of claim 1 in which the sample port comprises co-aligned through holes in the first and intermediate layers.

5 3. The device of claim 1 in which the first stop junction further comprises a second through hole aligned with the first through hole, the second through hole being overlaid with a fourth layer.

10 4. The device of claim 1, further comprising a bypass channel, to provide an additional path from the first channel to the bladder, without traversing the first measurement area and first stop junction.

15 5. The device of claim 1 in which at least the first or second layer is substantially transparent adjoining the first measurement area, and the physical parameter that is measured is optical transmission.

20 6. The device of claim 5 further comprising a reflective surface adjoining the first measurement area.

7. The device of claim 1 in which the physical parameter of the sample undergoes a change in the measurement area.

25 8. The device of claim 7 in which the first measurement area contains a composition that facilitates blood clotting, the biological fluid is whole blood, and the property being measured is prothrombin time.

9. The device of claim 8 in which the composition comprises thromboplastin.

5 10. The device of claim 1 further comprising a filter adjoining the sample port for filtering the biological fluid being introduced into the sample port.

11. The device of claim 10 in which the filter comprises an anisotropic membrane.

10 12. The device of claim 11 in which the filter material is polysulfone.

15 13. The device of claim 1 further comprising at least one additional measurement area between the first measurement area and the stop junction.

20 14. The device of claim 1 further comprising at least one alternate fluidic path from the first channel to the bladder, each such alternate path including a corresponding measurement area and stop junction.

25 15. The device of claim 4 in which the first measurement area contains a composition that facilitates blood clotting, the biological fluid is whole blood, and the property being measured is prothrombin time.

16. The device of claim 15 further comprising at least one alternate fluidic path from the first channel to the

bladder, each such alternate path including a corresponding measurement area and stop junction.

5 17. The device of claim 16 in which a first alternate path is to a measurement area that overcomes the effect of an anticoagulant and a second alternate path is to a measurement area that partially overcomes the effect of an anticoagulant.

10 18. The device of claim 17 in which the measurement area in the first alternate path comprises thromboplastin, bovine eluate, and recombinant Factor VIIa and the measurement area in the second alternate path comprises thromboplastin and bovine eluate.

15 19. The device of claim 13 further comprising at least one set of channel, measurement area, and stop junction between the first stop junction and first bladder and, adjoining the first bladder, an additional bladder for each such set.

20

20. The device of claim 19 further comprising a bypass channel from the first channel to the first bladder and an additional bypass channel from the channel of each additional set to the corresponding additional bladder.

25

21. A fluidic diagnostic device for measuring an analyte concentration or property of a biological fluid, comprising

a first layer, which has a resilient region over at least a part of its area, and a second layer, separated by an intermediate layer, in which recesses in a first surface of the intermediate layer form, with the first layer,

- a) a sample port for introducing a sample of the biological fluid into the device;
- b) a measurement area, in which the sample undergoes a change in a physical property that is measured and related to the analyte concentration or property of the fluid;
- c) a channel, having a first end and a second end, to provide a fluidic path from the sample port at the first end through the measurement area; and
- d) a bladder, at the second end of the channel, comprising the resilient region in the first layer and having a volume that is at least about equal to the combined volume of the measurement area and channel; and

a stop junction in the channel between the measurement area and bladder that comprises two passages substantially normal to the first surface of the intermediate layer, each passage having a first end in fluid communication with the channel and a second end in fluid communication with a recess in a second surface of the intermediate layer, which recess provides fluid communication between the second ends of the passages.